



Panacea®

# AIR OVERLAY

## Owner's Manual

*Please keep and refer to this Owner's Manual.*

Thank you for purchasing a Direct Supply® Panacea® Air Overlay. Please read this entire guide carefully and keep it for future reference. This guide will provide you with instructions, warnings, warranty information and other important information about your air overlay. Share this information with those individuals who will be assembling, using, servicing, and/or cleaning the product to help ensure the overlay is cared for properly.

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# Introduction, Definitions & Symbols

## Introduction

The Direct Supply® Panacea® Air Overlay is designed to assist in the prevention and treatment of pressure injuries for long term care residents. The resident support surface fits most standard healthcare beds, and runs underneath the entire body. The air flotation system aids in pressure redistribution and relief, and helps maintain low interface pressures throughout the surface.

The Direct Supply® Panacea® Air Overlay uses a compressor-based control unit which provides alternating pressure. The inflation levels are designed to maintain low interface pressures throughout the overlay, to redistribute peak interface pressures during the cycle, and to further relieve peak pressure points as the cycle alternates.

## Contraindications

Patient conditions for which the application of pressure relieving therapy on an alternation system is contraindicated as follows:

- Cervical or skeletal traction
- Unstable spinal cord injuries

## Definitions & Symbols

**NOTE:** Indicates a tip.

**CAUTION:** Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property

**WARNING:** Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

 **⚠:** Attention. Read the instructions.

**DEVICE:** Your Direct Supply® Panacea® Air Overlay.

**YOU and YOUR:** The facility, community or other entity that has purchased the device.

**WE, US, and OUR:** Direct Supply Manufacturing, Inc.

# Product Description & Specifications

## Product Description

<b>Indications for Use:</b>	The Direct Supply® Panacea® Air Overlay is a flotation therapy device that provides pressure management to assist in the prevention and treatment of pressure injuries. The alternating pressure mode provided with the Direct Supply® Panacea® Air Overlay is indicated for use as a preventive tool against further complications associated with critically ill residents or immobility.	
<b>Air Cells:</b>	130 air-filled polyurethane air bubbles/cells are divided into two separate, alternating pressure zones. These air cells inflate to a height of 2¾".	
<b>Overlay Height:</b>	Air Overlay	The total pressure-management surface height is 2¾".
<b>Overlay Placement:</b>	The overlay should be placed directly on an existing healthcare mattress of an appropriate size.	
<b>Pressure Management:</b>	This overlay system is designed to provide pressure management for the prevention and treatment of pressure injuries.	

### Control Unit

<b>Power on/off switch:</b>	Powers the control unit on and off.
<b>Firmness dial:</b>	Adjusts the pressure within the system.

## Product Specifications

<b>Certificates and Fire Ratings</b>	Meets California Technical Bulletin 117 (CA 117) ANSI/AAMI ES60601-1:2005 +C1 (2009) +A1 (2012) +A2 (2010) CAN/CSA-C22.2 No. 60601-1:14 ANSI/AAMI HA60601-1-11:2015 CAN/CSA C22.2 No. 60601-1-11:15 IEC 60601-1-6:2010 + A1:2013 CAN/CSA-C22.2 No. 60601-1-6A:11 - Amendment 1:2015 to CAN/CSA-C22.2 No. 60601-1-6:11	
<b>Control Unit</b>	120VAC, 60Hz	
<b>Surface Sizes</b>	Air Overlay	35"W x 2¾"H x 72"L, 250 lb weight capacity
<b>⚠ Check the weight capacity of the bed to make sure both the mattress and bed are capable of supporting additional weight</b>		
<b>Operating Mode</b>	Panacea Air Overlay – Alternating Pressure  Provides 8 minute loading and unloading cycle designed to maintain low interface pressures throughout the overlay, to redistribute peak interface pressures during the cycle.	

# Technical Description

## Technical Description

Direct Supply® Panacea® Air Overlay is designed and manufactured to meet the most demanding environment. The specifications are listed below:

### Specifications

Item Specification	
<b>Power supply</b>	100-127 VAC, 50/60Hz, 14 W
<b>Pressure Range</b>	30-120mm Hg
<b>Cycle time</b>	12 min for 50Hz, 60Hz
<b>Dimension</b>	29cm x 12cm x 9.8 cm (10.8" x 4.7" x 3.9")
<b>Weight</b>	1.1kg (2.43 lbs.)
<b>Environment / Temperature Operation:</b>	32°F – 104°F
<b>Humidity Operation:</b>	30% – 75% non-condensing

### NOTE:

The specifications also apply to those areas operating with the same power supply.

# Warnings


## Warnings

Read and follow all directions and warnings before using this device.

### **WARNINGS**

1. Failure to comply with all directions and warnings may result in injury or death; use only as directed.
2. This device is designed for use on static mattresses only. **DO NOT** use this device on alternating pressure or lateral rotation mattresses.
3. Due to the alternating pressure feature of the overlay, some devices and products may **NOT** be appropriate for use with this device. **DO NOT** use pressure pad alarm or alert systems in conjunction with the overlay.
4. This device is not suitable for all individuals. Other devices may be required.
5. Inspect the device for damage before each use and **DO NOT** use if device appears to be damaged or not functioning properly.
6. **NEVER** alter the device in any way.
7. This device is designed for indoor use only within close proximity to skilled caregivers.
8. The Air Overlay is **NOT** designed to operate with patients weighing more than 250 lbs.

**NOTE:** *User's body can not exceed the width of the overlay.*

 **WARNING:** This device is designed to assist in the prevention and treatment of pressure injuries and may require other equipment. This may include, but is not limited to:

1. Bed rails for repositioning and fall prevention.
2. Resident monitoring devices for elopement prevention.
3. Other devices as specified by the caregiver.

### **GROUNDING INSTRUCTIONS**

#### **Three-wire plug ground instructions**

This device is for use on a nominal 120V circuit. This device should be grounded. In the event of an electrical short circuit, grounding reduces the risk of electric shock by providing an escape wire for the electric current.

### **DANGER**

***Improper use of the grounding plug can result in a risk of electric shock.***

**⚠ WARNING:** To reduce the risk of electrocution:

1. **ALWAYS** unplug this unit immediately after using.
2. **DO NOT** operate near water.
3. **DO NOT** place or store device where it can fall or be pulled into a tub or sink.
4. **DO NOT** place in or drop into water or other liquid.
5. **DO NOT** reach for a device that has fallen into water. Unplug immediately.
6. **DO NOT** remove control unit cover. Risk of electrical shock.

**⚠ WARNING:** To reduce the risk of burns, fire or injury to persons:

1. Use this unit only for its intended use as described in the operating instructions.
2. **NEVER** operate this device if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the unit for examination and repair.
3. Keep the cord away from heated surfaces.
4. **NEVER** drop or insert any object into any opening or hose.
5. **DO NOT** use outdoors.

**⚠ WARNING**

This device is only a tool to assist with pressure reduction as part of an overall care plan. Failure to comply with all instructions, warnings and precautions or using the device for a purpose other than the recommended use could result in bodily injury or death.

This device is not designed to replace good care giving practices including, but not limited to:

- Direct patient supervision;
- Adequate care plans and training for staff personnel for entrapment and fall prevent.
- Inspection and testing before use.

**⚠ WARNING:** This device is only one element of care in the prevention and treatment of pressure injuries by medical professionals and skilled caregivers to assist in the treatment and prevention of decubitus ulcers for residents under their care. This device is not designed to and cannot replace good care giving practices and treatment including, but not limited to:

- Appropriate nutrition and hydration, frequent positioning, routine skin assessment, wound treatment, infection control, and other generally accepted standards of care and prevention.
- Adequate training for and precautions by staff personnel for bed entrapment.
- Selection of an appropriate bed system to use with the device and proper maintenance and use of the device.
- Testing of the device before each use.

# Directions for Use

## Directions for Use

1. Place the Direct Supply® Panacea® Air Overlay on top of the mattress (not supplied) with the hoses exiting at the foot of the bed.
2. Secure the overlay to the mattress by tucking the flaps located at the head and foot-ends under the mattress to prevent movement.
3. Hang the control unit on the end of the bed using the hangers, or place on a stable horizontal surface.
4. Ensure that the air lines are not “kinked” or “twisted”. Connect the overlay to the control unit by pushing the connector into the air ports located on the side of the pump. The hoses can be connected to either port on the pump unit.
5. Ensure that the electrical power source, if switched, is in an OFF position, then plug in the power cord and switch to ON. The POWER ON lamp is now illuminated.
6. Set the firmness level to the highest setting and allow approximately 20 minutes for the overlay to fully inflate.
7. After preparing the overlay surface with appropriate linens (not included), place the user on the overlay.
8. Decrease firmness if necessary for user comfort, support, and immersion into the overlay for optimal pressure redistribution.
  - a) A common method to check if suitable pressure is selected by sliding one hand between the air overlay and the air/foam base under the user’s buttocks. Users should be able to feel the space between their hand and the user’s buttocks with the acceptable range being 25-40mm (1" to 1½"). This hand check procedure is issued by AHCPR (Agency for Health Care Policy and Research).
  - b) Adjust the firmness by turning the dial; counterclockwise for more immersion (if too much space during hand check, too firm) or clockwise for less immersion (not enough space during hand check, too soft).

**⚠ CAUTION:** Be careful not to puncture the overlay with needles or sharp instruments. This may result in loss of integrity of the cover or internal air system.




# Transportation & CPR

## Transportation

Turn the pump off and unplug from the electrical source.

You may now transport the user while in bed. A properly sealed overlay will continue to support a user for approximately one hour without power. It is not possible to provide an exact time because it is dependant upon on the user's weight. Reattach the pump as soon as possible to restore overlay performance.

** WARNING: DO NOT attempt to use the overlay as a carrying device as it is not designed to carry a user's weight unsupported.**

## CPR

The standards for life support recommended by the American Heart Association recommend a hard level surface for performing CPR, moving the person to the floor if possible. If unable to move the user to another surface to perform CPR, place a crash board underneath the patient and follow appropriate CPR procedures.

To deflate the overlay for CPR function, pull the hoses from the pump allowing air to escape. The control unit should be turned off and/or removed to prevent the overlay from re-inflating during CPR.

In case of emergency, use a scissors or knife to cut the hose and/or the air cells in the overlay.


# Cleaning

## Cleaning and Disinfecting

### OVERLAY

Approved products for cleaning the cover include standard hospital-approved tuberculocidal disinfectants such as quaternary ammonia, germicidal phenols, or soap and water. Use products in dilutions as specified on the manufacturer's label. **DO NOT USE BLEACH.** For soils or stains, wipe fabric clean with neutral suds and lukewarm water. For hard to clean spots, use standard liquid household/vinyl cleaners with a soft bristle brush. **DO NOT USE HARSH SOLVENTS OR CLEANERS.**

### CONTROL UNIT

 **WARNING:** Before attempting to clean the control unit, turn off unit and disconnect the power cord from the power source.

**DO NOT HEAT, STEAM AUTOCLAVE, OR IMMERSE THE CONTROL UNIT IN LIQUIDS.**

1. Follow the preparation instructions provided with the germicidal detergent/disinfectant solution to prepare the required amount of disinfectant solution or mild detergent solution.
2. Pour required amount of the germicidal solution into a spray bottle.
3. Using a brush or cloth, wipe off dust. If necessary, spray the exterior of the top and the bottom enclosures, power cord and the cord plug with the prepared disinfectant or detergent solution. Using a damp cloth wipe down the sprayed surface cleanly.

 **NOTE:** *Do not spray excess amount of solution on the control unit.*

4. Once the control unit is clean, wipe the unit, the power cord and the cord plug down with a clean dry cloth.
5. Place the control unit to dry in a cool and dry area for an hour before operating the unit again. If the control unit is not used immediately, place the control unit in a plastic bag and store it in a storage area.

# Preventive Maintenance & Storage

## **Preventive Maintenance**

It is important to periodically test the Panacea Air Overlay control unit to verify the proper functionality. Lack of regular maintenance can result in poor or reduced support.

Check for air leaks and repair leaks following the patch kit instructions.

## **Storage**

1. After cleaning the overlay and drying it completely it may be folded to smaller size for easier storage.

***Avoid storage of other equipment on top of the overlay.***

2. The unit should be stored in a clean, dry environment. Follow the recommended temperature and humidity guidelines when storing the unit:
  - Temperature: 59°F – 122°F
  - Humidity: 10% – 90% (at 104°F)

# Troubleshooting Guide

## Troubleshooting Guide

### ***Overlay will not inflate or half the cells are not inflating:***

- Disconnect the control unit from the overlay and make sure that air is flowing from the open ports. This is done by disconnecting the control unit from the overlay and physically feeling the air blowing out from one port and then the other. It may take several minutes to switch from one port to the other depending on the control unit's cycle time. If the control unit is not blowing air out of the ports, call for service.
- Check to make sure that the control unit is on.
- Check to make sure the unit is plugged into a live electrical outlet and that the outlet is not operated by a switch that is in the off position.
- Check to make sure that the control unit is properly connected to the overlay.
- Visually inspect each air cell to make sure there are no cuts, punctures or tears in the material. If defect is found, use repair kit provided to patch the leak. If a defect cannot be repaired, call for repair or replacement of the defective component.
- Check to make sure that there are no kinks or leaks in the hoses. If a defect is discovered, call for repair or replacement of defective component.

# Limited Warranty

## Limited Warranty

We offer to you, as the original purchaser, a warranty for the Direct Supply® Panacea® Air Overlay. Our warranty applies for the limited warranty period stated below. If any device or device part listed below is defective in material or workmanship during the applicable limited warranty period, we will repair or replace it at our cost. Please note that the decision to repair or replace a device or device part will be at our discretion. Our warranty applies only if the device is properly maintained by the original purchaser for normal, indoor use and does not cover normal wear and tear, modification of the device, or damage caused by abuse, improper use, failure to maintain, use which exceeds the published device limitations, or the combination of any device with another product. In addition, our warranty does not cover fading, characteristics or natural variations in fabric, texture, colorfastness, stains, spills, or exposure to chemicals, odors, heat or light. In certain cases, we may provide you repair or adjustment instructions and/or replacement parts, and ask you to perform a repair or adjustment or replace a defective part.

Our warranty gives you specific legal rights, and you may also have other rights, which vary, from state to state. Please note that our limited warranty period begins when we ship the device to you. The limited warranty period and our obligations under the warranty end once you transfer the device to someone else, or at the end of the applicable limited warranty period identified below, whichever is earlier.

Product/Part	Warranty Period & Coverage (Parts)
Electrical Components	18 months
Overlay	1 year

Anticipated Usable Device Life is based on normal use with proper maintenance, cleaning and storage. You should still inspect, monitor and care for the device as described in this guide, as the device may need to be replaced sooner than anticipated in particular situations.

DIRECT SUPPLY MANUFACTURING, INC. MAKES NO IMPLIED WARRANTIES OF

## Limited Warranty *(cont.)*

MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; THESE AND ALL OTHER IMPLIED WARRANTIES ARE SPECIFICALLY DISCLAIMED. TO THE FULLEST EXTENT ALLOWED BY LAW, DIRECT SUPPLY MANUFACTURING INC. WILL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, OR LOST PROFITS THAT MAY RESULT FROM THE DEVICE OR YOUR USE OF OR INABILITY TO USE THE DEVICE EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. OUR TOTAL LIABILITY TO YOU, IF ANY, IS LIMITED TO THE PRICE OF THE DEVICE OR SERVICE GIVING RISE TO YOUR CLAIM. Some states do not allow an exclusion or limitation of incidental or consequential damages or how long an implied warranty lasts, so the above limitations or exclusions may not apply to you. If implied warranties are not excluded, and to the extent allowed by law, we limit any and all implied warranties to the applicable warranty period identified above. Except for rights under any applicable state law, the remedies provided under this warranty are your sole and exclusive remedy for any breach of our warranty and state the entire limit of our responsibilities.

# Customer Service

## **Customer Service**

Our promise to you is that you will have a convenient and easy ordering experience, receive a quality mattress and enjoy outrageous customer service. If you have any questions about the unit you have purchased or would like to request warranty service, please contact your distributor.



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